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P194

Safety And Behavioral Effects Of A Single Session Of High Frequency Repetitive Transcranial Magnetic Stimulation In Chronic Stroke.

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INTRODUCTION: Non-invasive electromagnetic brain stimulation might be of value to reduce motor deficits after stroke, by either increasing ipsilesional excitability or decreasing contralesional excitability. The safety of these methods requires further study. The current study examined safety and behavioral effects of increasing ipsilesional excitability, delivered during a single session of high frequency repetitive transcranial magnetic stimulation (rTMS) to the ipsilesional primary motor cortex. **METHODS:** This unblinded, active-treatment-only, single-dose, two-center study was approved by the U.S. FDA and local IRBs. Entry criteria included age 18–85 years; infarct > 11 weeks prior, hemispheric in location, and > 15 mm from the stimulation target; and no contraindication to TMS or MRI. Anatomical MRI was obtained and used to define the rTMS target, the center of the hand area knob within gray matter of posterior precentral gyrus. Each subject's head was registered to his/her MRI using frameless stereotaxy. Single pulse rTMS applied to the stroke-affected hemisphere with a figure-of-8 coil defined the motor threshold (0–100% of TMS device output) for the paretic first dorsal interosseus muscle, after which rTMS was applied at 90% of this threshold. If TMS elicited no motor response, stimulation was set at 65% of device output. rTMS application consisted of 40 trains, each having 40 pulses (20 Hz X 2 sec), each train separated by 28 sec

of silence, for a total of 1600 pulses over 20 min. Subjects were assessed before, during the hour after, and 1 wk after rTMS. RESULTS: The 12 subjects enrolled were 4.7 ± 4.9 y post-stroke (mean \pm SD), age 67 ± 12 y, baseline NIHSS score 4 ± 2 , and arm motor Fugl-Meyer 34 ± 16 (of 66). rTMS was well tolerated and without adverse events. SBP increased from pre- to immediately post-rTMS by 7 mm Hg ($p=.043$). None of the 7 behavioral measures assessed across rTMS showed a decrement, and several showed improvement. The total # pegs placed on 9-hole pegboard increased 83% ($p=0.04$) from pre- to 1 hr post-rTMS, accounted for by 4/12 subjects, among whom baseline motor status was significantly greater than those not showing pegboard gains; a trend ($p=.057$) suggested retention of these gains at 7 days post-rTMS. Grip strength and range of motion each increased ($p<.03$ each), in 7 or more subjects, during the hour post-rTMS. Arm motor Fugl-Meyer score increased by 1.5 ± 1.7 points by 1 week post-rTMS ($p<.02$), a gain seen in 8/12 patients. CONCLUSIONS: A single session of high frequency rTMS to motor cortex was safe. Results suggest gains in several measures of arm motor function, though no control group was included. Gains lasted days beyond the session, and might be most likely in those with lesser deficits. Future studies can have larger sample size, include sham-treatment controls, employ multiple rTMS sessions, and evaluate interactions with concomitant secondary therapies.